GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:4150
ANSWERED ON:25.08.2004
LICENCES FOR DRUGS
Bhadana Shri Avtar Singh

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the number of licences for drugs issued in the country for manufacture of medicines;

(b) whether majority of these licences have been issued for Small and Medium Scale Units;

(c) the details of the licensed companies which have no manufacturing base in the country and get their products manufactured on loan licence from SME; and

(d) the reaction of the Government in this regard?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a):Under the provisions of Drugs and Cosmetics Act, 1940 and rules thereunder, the responsibility to grant licences for manufacture of drugs rests with the Drugs Controllers appointed by the State/UT Governments. As per the feedback available, there are about 19,830 licences granted in the country for manufacture of medicines. This ranges from manufacture of drugs formulations, bulk drugs, vaccines, devices, repacking of drugs, blood banks, Ayurvedic and Homeopathic drugs etc. as well as manufacture of drugs on loan licences.

(b): Yes Sir.

(c)&(d):Under the said rules, it is provided that the Licensing Authority may issue a loan licence to an applicant who does not have his arrangements for manufacture but who intends to avail himself of the manufacturing facilities owned by another licensee. The State Licensing Authority, before grant of a loan licence is required to satisfy itself that the principal manufacturing unit has adequate equipment, staff, capacity for manufacture on behalf of the applicant firm for a loan licence. The details of the licensed companies which have no manufacturing base in the country and get their products manufactured on loan licence from SME is not maintained centrally.